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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,223	05/07/2001	Antony Walter Anson	78014.018	2854

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Intellectual Property Dept.
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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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06/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No. 09/762,223	Applicant(s) ANSON ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51, 53, 55-55-64, 67, 68 and 70-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51, 53, 55-55-64, 67, 68 and 70-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 76-78 are rejected under 35 U.S.C. 101, because they claim an artery, an unpatentable part of the human body, as structural part of the invention. The Examiner suggests language to the effect of the fixator being --configured to be attached to an artery--.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect paragraphs B.a.(3) and B.b(3), the "artery wall," an unpatentable part of the human body, is essentially claimed as structural part of the invention. The Examiner suggests language such as --is configured to bias the support members towards the artery wall— or --configured to bias the dilating member towards and into contact with the inner artery wall--. With respect to claim 72, "the non-sharpened portion of the first parts and the non-sharpened portion of the second parts" lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 51, 53, 55 -61, 63, 70, 73, and 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (6,994,713). Berg et al. discloses, at least in figures 1,13-15 and 18 and in col. 2, lines 3-55; col. 4, lines 4-65; and col. 7, line 14 to col. 8, line 26; a fixator for retaining a graft (30) on an artery, where the fixator includes a plurality of first parts (14 at one end), at least one second part (14 at another end), a resilient member (16) connecting the first and second parts, where the resilient member biases the first and second parts toward each other into a retaining configuration (e.g., see fig. 18), where the first and second parts are moveable into an open configuration as claimed, where only the first and second parts extend from the resilient member, where the resilient member has a cross-sectional area substantially equal to the cross-sectional area of the first or second parts in their open configuration, where the first and second parts form arcuate shapes, where the parts are integral, where the fixator has equal numbers of first and second parts, where the device is formed of and linked together by wires (thin, elongated structures, see fig. 13) and from a shape memory

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alloy (e.g., nitinol), and where each elongated member is normally biased into the retaining configuration.

7. Claims 51, 64, 67, 68, 74, 75, 80, 81, 82, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Shein (3,527,223). Shein discloses a fixator at least in figures 1 and 3-5 and in col. 1, line 67 to col. 2, line 16. With respect to claims 51, 74 and 75, Shein discloses a fixator including a plurality of first parts (24, 26), at least one second part (20, 22), a resilient member (14) connecting the first and second parts, where the resilient member biases the first and second parts toward each other into a retaining configuration (see figs 1, 4, and 5), where the first and second parts are moveable into an open configuration as claimed, where only the first and second parts extend from the resilient member, where the resilient member has a cross-sectional area substantially equal to the cross-sectional area of the first or second parts in their open configuration, and where the first and second parts are respectively adjacently aligned in abutment with each other (at 16 and 18 when, for example, human fingers pinch the first and second parts). With respect to claims 64, 67, 68, and 80-84, Shein discloses a fixator consisting of elongated members (one elongated member is the combination of 24, portion of 14 and 20 and another member is the combination of 26, portion of 14 and 22), each elongated member extending between first and second parts, where the first and second parts are sharpened (inherently along the longitudinal edges of 24, 20, 26, and 22 after "slices" are made at 16 and 18. That is, a wire of circular cross-section is formed into elongated members, each having a semicircular cross-section have tapering, longitudinal edge portions deemed to be "sharpened"

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relative to the circular cross-section of the fixator), where each elongated member has an open configuration (see phantom image of 10 in fig. 1 or see fig. 3) with first and second parts that are distant and aligned along a common axis, first and second parts adjacently situated with their lengths in abutment (at 14 and/or as seen in figs. 1 and 3, at 16 and 18) and substantially coaxial, and where the fixator has a substantially uniform cross-sectional area as it extends from its first parts to its second parts; and a retaining configuration (see figs 1 and 5), where the first and second parts are closely spaced, where the each elongated member is biased or bent towards the retaining configuration, where the first and second parts define terminal ends; where the fixator, when in the retaining configuration is shorter along a direction aligned along the linear axis (i.e., parallel to linear axis) than when in the open configuration; where the first and second parts comprise wires (Note: Claim 82 is a product-by-process claim, which is not construed as being limited to the product formed by the specific processes recited; i.e., connecting of wires by weld, sheath, a bush, a crimp, or by wire.), and where the first and second parts are each sharpened at a location most distant from the resilient member (i.e., the side edges of the first and second parts are tapering along the entire length of each of the first and second parts),.

Note: The introductory statement of intended use (“for retaining a graft on an artery”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Shein’s device, which is capable of being used as claimed if one desires to do so.

Allowable Subject Matter

8. Claim 62 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

9. Claim 72 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a fixator included in a kit, where the fixator includes, inter alia, a plurality of first parts, at least one second part, and a resilient member connecting the first and second parts; and where the kit includes, inter alia, a device for supporting a catheter having a locating member, a plurality of support members, and resilient member, and/or a device for dilating an artery having a locating member, a plurality of dilating members, and a resilient member. The prior art of record also does not disclose that fixator includes, inter alia, a substantially uniform cross-sectional area between a non-sharpened portion of the first parts and a non-sharpened portion of the second parts when the elongated members are in their open configuration.

Response to Amendment

11. Applicant's arguments or comments with respect to claims 68, 71, 72, and 81 have been considered but are moot in view of the new ground(s) of rejection.

With respect to arguments regarding the rejection based on 35 U.S.C. 101: The rejection remains, since the claims, as recited and given the broadest reasonable

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interpretation, can encompass a human being. That is, the artery, as claimed, is nonstatutory subject matter.

Some background on 35 U.S.C. 101: On April 7, 1987, then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, set forth PTO policy on this issue in the form of a notice entitled “Animals – Patentability”. The notice affirmed that the “Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101” and relied on the now famous Supreme Court decision *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105, last two paragraphs. However, Commissioner Quigg’s notice also went on to affirm the long-standing PTO principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101. Specifically, the Commissioner stated that a “claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101” since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Beyond the statute itself, proper authority for the rejection is Commissioner Quigg’s notice which was published at 1077 OG 24 (April 21, 1987).

The rejection of claims 68, 70, 71, and 81 under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

With respect to arguments regarding the rejection based on Berg: Berg indeed discloses that resilient member 16 has a cross-sectional area at least substantially equal to the cross-sectional area of the first or second parts (i.e., the claims recite a

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plurality of first or second parts, which collectively define a cross-sectional area substantially equivalent to the cross-sectional area of the resilient member), but the resilient member has a cross-sectional area greater than the cross-sectional area of singular first part or second part. Additionally, Berg indeed discloses a device formed of wires. According to Merriam-Webster's Collegiate Dictionary, 10th edition, "wire" can be defined to include "metal in the form of a usu. very flexible thread or slender rod." And given the broadest reasonable interpretation of "wire," Berg's structure, as shown in fig. 13, can be said to comprise slender rods of metal.

With respect to arguments regarding the rejection based on Shein: Applicant has not claimed that the ends or tips of the first and second parts are sharpened. As suggested by the allowable subject matter of claim 72 (indicated above), the locations of the sharpened and non-sharpened portions of the first and second parts should be defined in the claims. As mentioned in the rejection above and for the claims as recited, the Examiner has deemed the side, longitudinal edges of the first and second parts to be sharpened (i.e. side portions tapering to an edge when the wire is sliced or when the first and second parts are molded) relative to portion 14 of the Shein's device.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773